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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/821,691	04/08/2004	Jackie R. See	52391/WPC/O194	1374

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EXAMINER	
KISHORE, GOLLAMUDI S	
ART UNIT	**PAPER NUMBER**
1612	

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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/821,691	SEE ET AL.	
	Examiner	Art Unit	
	Gollamudi S. Kishore, Ph.D	1615	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *08 April 2004*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-34* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-34* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Claims included in the prosecution are 1-34.

Claim Rejections - 35 U.S.C. § 102

1. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless --

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

2. Claims 1-2, 4-7, 15-18 and 20-34 are rejected under 35 U.S.C. 102(b) as being anticipated by Diminski (New Generation of Vaccines, 1993).

Diminski teaches lyophilized liposomes containing hepatitis antigen for use as a vaccine (note the Introduction and Materials and Methods). Instant claims do not recite any percentages of specific populations of liposomes based on size. Therefore, the burden is upon applicant to show that the lyophilized liposomes are different from instant lyophilized liposomes.

Claim Rejections - 35 U.S.C. § 103

3. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

4. Claims 1-2 and 4--34 are rejected under 35 U.S.C. 103(a) as being unpatentable over Sato (5,573,779) or Aramaki (Pharmaceutical Research, 1993) in view of Diminski cited above by itself or in further in view of Gregoriadis (Liposomes as drug carriers, 1988).

Sato teaches oral liposomal vaccine formulations which reach Peyer's patches. The method of preparation includes vortexing or ultrasonication and filtration (note the abstract, columns 1-4, examples and claims). Sato however, does not teach instant antigens. Sato also does not teach the lyophilization of the liposomes and the sizes of the liposomes.

Similarly, Aramaki teaches the oral administration of antigens encapsulated in liposomes to he taken up by Peyer's patches (note the abstract, Materials and Methods, and discussion). Aramaki however, does not teach instant antigens. Aramaki also does not teach the lyophilization of the liposo10mes.

What is lacking in Sato, and Aramaki are the teachings of lyophilization of the liposomes and the use of specific claimed antigens.

Diminski as pointed above teaches the use of liposomes containing hepatitis

antigen in lyophilized form for use as a vaccine.

Gregoriadis while discussing the immunoadjuvant action of liposomes teaches that it is sometimes preferable that liposomes containing antigens be freeze-dried (note the entire article; in particular pages 282 and 286).

It would have been obvious to one of ordinary skill in the art to lyophilize the liposomes since both Diminski, and Gregoriadis teach that lyophilization is routinely practiced in the art and that it is sometimes preferable. In the absence of showing unexpected results, it is deemed obvious to an artisan to use any antigen including claimed antigens in Sato's or Aramaki's teachings with the expectation of obtaining similar antibody response. The criticality of the different sizes of the liposomes is unclear to the examiner since both Sato and Aramaki are both directed to the successful delivery of the liposomes to Peyer's patches.

5. Claim 3 is rejected under 35 U.S.C. 103(a) as being unpatentable over Sato (5,573,779) or Aramaki (Pharmaceutical Research, 1993) in view of Diminski cited above by itself or in further in view of Gregoriadis (Liposomes as drug carriers, 1988), further in view of Geary (5,382,435).

The teachings of Sato, Aramaki, Diminski and Gregoriadis have been discussed above. What is lacking in these references is the teaching of enteric coating over the lyophilized preparations.

Geary teaches that Peyer's glands exist in the jejunum particularly in the lower portion thereof and in order to deliver acid and alkali labile agents to Peyer's patches the compositions have to be enterically coated. Geary's formulations include enteric

coated liposome formulations for the delivery of pharmaceuticals including oral vaccines selectively to Peyer's patches. The composition is administered orally in the form of a capsule (note the abstract, col. 1, lines 35-39; col. 2, lines 36-68 and claim 6).
To use enterically coated capsules in the teachings of Sato, Aramaki. Diminski and Gregoriadis would have been obvious to one of ordinary skill in the art since such enteric coating would enable the antigens in the compositions to reach Peyer's patches selectively.

6. Claims 15 and 19 are rejected under 35 U.S.C. 103(a) as being unpatentable over Sato (5,573,779) or Aramaki (Pharmaceutical Research, 1993) in view of Diminski cited above by itself or in further in view of Gregoriadis (Liposomes as drug carriers, 1988), further in view of Fullerton (4,235,877).

The teachings of Sato, Aramaki, Diminski and Gregoriadis have been discussed above. What is lacking in these references is the teaching of the claimed specific antigens.

Fullerton while disclosing liposomal formulations containing bacterial and viral antigens teaches that liposomally encapsulated antigens are more active than free antigens. The antigens taught by Fullerton include hepatitis and influenza viruses (note the abstract, col. 2, line 21 et seq., and Examples).

The use of the antigens taught by Fullerton in the teachings of Sato, Aramaki, Diminski and Gregoriadis would have been obvious to one of ordinary skill in the art since Fullerton teaches that these antigens are more active in liposomes than free antigens.

7. Claims 11 is rejected under 35 U.S.C. 103(a) as being unpatentable over Sato (5,573,779) or Aramaki (Pharmaceutical Research, 1993) in view of Diminski cited above by itself or in further in view of Gregoriadis (Liposomes as drug carriers, 1988), further in view of Barchfield (5,709,879).

The teachings of Sato, Aramaki, Diminski and Gregoriadis have been discussed above. What is lacking in these references is the teaching of HIV antigens. Barchfield discloses high levels of immune response to liposomally encapsulated HIV antigens, gpl20 and RT6 (note the abstract and col. 7, lines 24-33). The use of HIV antigens taught by Barchfield in the teachings of Sato, Aramaki, Diminski and Gregoriadis would have been obvious to one of ordinary skill in the art since Barchfield teaches higher levels of immune response by such an encapsulation.

Double Patenting

8. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

9. Claims 1-34 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-7 and 15-34 of US 6,015,576. Although the conflicting claims are not identical, they are not patentably distinct from each other because instant generic claims include the three different sizes of liposomes in the claims of said patent. Though instant claims 22-34 recite the use of the product by a specific process they are still the use of the same product. Since instant claims do not recite any specific amounts of each population, these claims are included in the rejection

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

10. Claims 1-34 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-49 of US 6,117,449. Although the conflicting claims are not identical, they are not patentably distinct from each other because instant generic 'antigens' includes the hepatitis C antigens in the claims of said patent. Instant method claims are drawn to the use of the same composition in claims 8-13 and 32-49 of said patent and therefore the rejection is made over said claims also.

11. Claims 1-34 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-51 of U.S. Patent No.

6,207,185. Although the conflicting claims are not identical, they are not patentably distinct from each other because the claims in said patent recite HIV antigens and specific amounts of each population of liposomes whereas instant claims are generic both. It would have been obvious to one of ordinary skill in the art to vary the sizes of the liposomes with the expectation of obtaining the best possible results.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Gollamudi S. Kishore, Ph.D whose telephone number is (571) 272-0598. The examiner can normally be reached on 6:30 AM- 4 PM, alternate Friday off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Woodward Michael can be reached on (571) 272-8373. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/S Kishore/

Gollamudi S Kishore, Ph.D
Primary Examiner
Art Unit 1615

GSK